REMARKS

The Office Action dated April 7, 2009, and the references cited in the previous Final Office Action (dated November 18, 2008) and the grounds for rejection set forth therein, have been considered.

Applicants have amended the claims to remove the claimed subject-matter of (previously canceled) dependent claim 9 from each of the independent claims. Applicants previously noted their strong belief that it was not necessary to incorporate claim 9 into claim 1 to recite patentable subject-matter. The presently pending independent claims remove the claimed subject-matter of previously canceled claim 9. The subject matter of claim 9 is again presented in new dependent claims 25 and 26.

Applicants request favorable reconsideration of the grounds for rejection of the previously pending claims in view of Applicants' amendments to the claims and remarks addressing the shortcomings of the prior art with regard to particular recited elements of the claimed invention. Please charge any fee deficiencies to Deposit Account No. 12-1216.

Oath/Declaration Objection

The Office Action, at page 2 states that the Oath or Declaration is defective. However, The Declaration's handwritten changes were indeed accompanied by the inventor's signature in the line immediately above the handwritten changes. The Declaration, to which the current objection has been raised, was considered and accepted when filed in **2004.** Moreover, the Office Action's reference to 37 CFR 1.52(c) appears to be in error since this section discusses changes to the **specification**. Applicants are unaware of any question as to whether the stated citizenship and address of the inventor were correct. Applicants respectfully request reconsideration of the Office Action's position regarding the handwritten *citizenship and address of the inventor immediately below the inventor's signature.*

Rejection of Claims 1-8 and 10-24 Under Section 112, Paragraphs 1 and 2

Claims 1-8, and 10-24 presently stand rejected for failing to meet the clarity and enablement requirements under Section 112, paragraphs 1 and 2. Applicants have amended the claims (see, new dependent claims 25 and 26) to address the Section 112, paragraph 1 and

2 rejections set forth in sections 3-6 of the Office Action. Applicants note that probability functions (also probability density functions) were known at the time of filing the application, and the Office Action does not appear to object to the use of that term. The rejection appears to be the recitation of using a probability function to determine *optimum overlap* between consecutive signals. However, Applicants explain determining an optimum overlap between consecutive signals at paragraphs [0014, 0015, and 0016] of their Published Application (2005/0033199).

> [0014] According to the invention, signals are received from, e.g., a vessel wall in a preferably almost continuous motion, consecutive (groups of) frames still having a sufficient correlation to enable distillation of the relevant information. This can be determined by means of a probability function indicating the relation between consecutive images. By controlling the motion (or feeding back feedback position) related to this probability function, an optimum palpogram quality is obtained, which can even be more favorable than in a stationary arrangement.
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> [0015] The method preferably comprises the step of displaying elasticity and/or hardness parameters of the tissue surface or tissue volume part extending practically parallel to the direction of motion of the sensor, if required, combined with position information of the sensor and/or the tissue. The deformation can be determined with an acoustic or optical sensor detecting echographic or optical data.
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> [0016] In a further preferred embodiment, signals possessing an optimum overlap are received. An optimum overlap can be determined by means of a probability function displaying the similarity between consecutive signals.

Determining "optimum overlap" was defined in the specification and subsequently used in the claims. The specification explains how to obtain an "optimum overlap". The claimed invention is not limited to any particular probability function used to make the determination of optimal overlap for consecutive signal.

Previous Rejections (November 18, 2008) of the Claims Over Torp in view of Porat and Panescu

Summary of Applicants' Disclosed/Claimed Invention

Applicants' claimed invention is directed to a method and apparatus for generating hardness/elasticity information of tissue subject to a varying pressure as a sensor is drawn in a direction transverse to a measuring plane defined by the sensor. The exemplary embodiment discloses a three-dimensional imaging procedure/apparatus wherein an intravascular ultrasound transducer is withdrawn along a section of a blood vessel, subjected to varying pressure during a cardiac cycle, to render a three-dimensional representation of the hardness/elasticity of the vessel tissue. Moving the sensor along the tissue, in the case of a cardiac cycle, has the advantage of minimizing motion of an artery wall in particular circumstances described in paragraphs 0054 and 0055 of Applicants' published application. In particular, moving the sensor has the effect of fixing the sensor's position relative to the moving wall of the artery during a period within a cardiac cycle, thereby improving the quality of the palpogram. Thus, while moving the sensor along a vessel's length has the overall effect of providing an image of a length of a blood vessel, *in the short term* the movement of the sensor while acquiring ultrasound signal data within a portion of a cardiac cycle potentially minimizes the effect of an otherwise moving artery wall (in a transverse direction) during a single data acquisition period – such artery wall movement arising, for example, from blood pressure/flow variations during a heartbeat cycle.

Rejection of Claims 1-4, 6-8, 11, 13, 14, 18, and 21-23 As Obvious Over Torp in view of Porat

Applicants traverse the previous rejection of claims 1-4, 6-8, 11, 13, 14, 18 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over Torp et al. US Pat. No. 6,099,471 (Torp) in view of Porat et al. US Pub. No. 2003/0220556 (Porat).

Applicants, as a general matter, traverse the "grounds for combining" the teachings of Torp and Porat set forth in the first full paragraph at the top of page 5 of the Office Action. The claimed invention is directed to a method (e.g., independent claim 1) and apparatus (e.g., independent claim 13). The Office Action states that the combination of Torp and Porat would facilitate determining a tissue parameter *along the length of tissue*. The claimed invention, clarified by the previous amendment, is directed to acquiring signal data while the

sensor is moving in order to more closely track movement of tissue *as the signals are acquired by the sensor*. The claimed movement of the sensor has the effect of maintaining a "same field of view" for the sensor during the claimed signal acquisition step – not generating image data along the length of tissue. The movement of the sensor in the cited Porat reference is used to obtain image data for *a new area* of the imaged tissue. The combined teachings of Torp and Porat therefore neither disclose nor suggest Applicants' claimed invention. The absence of specifically recited claim elements is addressed herein below.

Independent Claims 1 and 13

Torp does not disclose "relating the strain to at least one of either hardness or elasticity parameters of the tissue" as recited in claim 1. As recited in claim 1 and disclosed in the Application, "generating hardness information of the tissue" is a primary function of Applicants' invention. *See,* Applicants' specification, paragraph [0002]. Moreover, Torp does not disclose a method comprising among other things, "[i]dentifying strain of the tissue" as recited in claim 1. Rather Torp discloses a method and apparatus for determining *strain velocity*. *See* Torp, Abstract. That is, Torp measures the *rate of change in strain*, as distinct from strain. *See* Torp, col.1, ll.30-31. Given the differences between what Torp and Applicants seek to measure (i.e. strain velocity in Torp versus hardness and elasticity in the Application), Applicants submit that the combined teachings of Torp and Porat do not teach each of the recited elements of independent claims 1 and 13, and therefore the previous Office Action has not established a *prima facie* case of obviousness with regard to Applicants' claimed invention that recites using strain (identified from signals acquired by a transversely moving sensor) to determine hardness or elasticity parameters of the tissue. The Office Action (November 18, 2008) admits that Torp does not disclose "moving the sensor along the tissue in a direction transverse to the measuring plane".

Regarding the (November 18, 2008) Office Action's assertions within the last paragraph of page 3, Applicants submit that Porat does not disclose a "sensor, where the sensor is moved during the receiving signals step: (a) in a direction transverse to the measuring plane, and (b) while the tissue is subject to a varying pressure" as recited in claim 1. The Office Action, citing paragraphs [0286] and [0298] of Porat, suggests Porat discloses a sensor which moves along the tissue in a direction transverse to the measuring plane. However, Porat, neither in these paragraphs nor elsewhere in the patent, discloses this

characteristic (i.e., moving the device while obtaining measurements). Porat does not disclose the direction of its sensor's (which Porat patent refers to as "device 200") motion, or specifically whether the sensor's direction of motion is transverse to the measuring plane. Further, Porat does not disclose "the tissue is subject to a varying pressure" during a receiving signals or measuring step. A notable aspect of Applicants' disclosure is that the sensor conducts its measurements while the tissue is subject to a varying pressure, possibly as a result of the natural heartbeat. *See* Applicants' specification, Paragraph [0056].

Claim 13 is patentable over Torp and Porat for reasons similar to those discussed for claim 1. Unlike Applicants, Torp does not disclose an "apparatus for generating hardness information of tissue" as recited in claim 13. Rather Torp determines strain velocity using ultrasound. *See* Torp, Abstract. Further, Torp does not "relate the strain to elasticity and/or hardness parameters of a tissue surface." Nor does Torp disclose a "display device for displaying elasticity and/or hardness parameters of the tissue surface." In fact, Torp does not concern elasticity or hardness of tissue whatsoever. Porat, also unlike Applicants claimed apparatus, does not disclose "a sensor movable through a blood vessel or body cavity for recording signals . . . [sensor] being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor" as recited in claim 13. Porat does not disclose the sensor's direction of movement, let alone that the sensor moves in a direction transverse to a measuring plane defined by the sensor. Additionally, Porat's sensor is not movable through a blood vessel or body cavity. Paragraphs [0096] and [0298] of Porat indicate that the sensor is placed on the "skin" of the body, preferably close to the "region-of-interest." The sensor is therefore, non-invasive and external to the body, and thus, cannot be movable through a blood vessel or body cavity.

Dependent Claims 2-4, 6-8, 11, 14, 18, 21-23

Claims 2-4, 6-8, and 11, which depend upon independent claim 1, are patentable over Torp in view of Porat for at least the reasons set forth above with regard to claim 1. Further, with respect to claim 3, neither Torp nor Porat disclose the "step of displaying elasticity and/or hardness parameters of a tissue surface or tissue volume part."

Claims 14, 18, and 21-23, which depend upon independent claim 13, are patentable over Torp in view of Porat for at least the reasons set forth above with regard to claim 13.

Further, with respect to claim 22, Porat does not disclose that its sensor is arranged in a catheter. Fig. 2c of Porat and accompanying descriptions disclose Porat's sensor (device "200" in Fig. 2c of Porat) is not a catheter, since a catheter is a long narrow tube.

Rejection of Claims 5, 10, 12, 15-17, 19, 20, and 24 Over Torp in view of Porat and Panescu

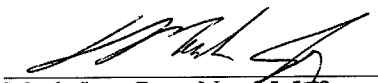
Applicants also traverse the previous rejection of claims 5, 10, 12, 15-17, 19, 20, and 24 under 35 U.S.C. 103(a) as being unpatentable over Torp in view of Porat and Panescu et al. US Pat. No. 5,848,969 (Panescu). Claims 5, 10, and 12, which depend upon independent claim 1, are patentable over Torp in view of Porat, and in further view of Panescu for at least the reasons set forth above with respect to claim 1.

Further, with respect to **claim 12**, Panescu does not disclose that "the tissue is an artery moving during the heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction, so that, during at least one detection period, the sensor has a fixed position relative to the wall of the artery." While Panescu's sensor is movable, Panescu does not disclose that the tissue is also moving while the sensor is receiving signals. In addition, Panescu does not disclose that the sensor is moving along a direction parallel to the tissue's direction of motion, such that the sensor has a fixed position relative to the tissue. According to Applicants' disclosure, the elements recited in claim 12 provide improved recording of hardness and/or elasticity properties. *See* Application, Paragraphs [0018], [0055]. Claims 15-17, 19, 20, and 24, which depend upon independent claim 13, are patentable over Torp in view of Porat and Panescu for at least the reasons set forth above with respect to claim 13.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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